How Clean is "Clean Enough" when Reprocessing Surgical Instruments?

Dr. Michelle J. Alfa, Ph.D., FCCM

Medical Director, Clinical Microbiology,

Diagnostic Services of Manitoba, Winnipeg, Canada

Disclaimers:

- ***Sponsored to give invited presentations at various National and International conferences by;***
  STERIS, 3M, J&J, Healthmark, APIC, CACMID, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.

The University of Manitoba has licensed Dr. Alfa's patent for Artificial Test Soil to Healthmark.

Opinion Leader Panel participation or Consulting Services for: 3M, J&J, STERIS, Olympus, bioMerieux, Serim, Borden Ladner Gervais LLP, various Canadian Healthcare facilities.

Research projects for:
3M, STERIS, J&J, Novaflux, Virox, Olympus, Medisafe, Case Medical, Province of Manitoba, Public Health Agency of Canada
(NOTE: no funds from these research projects comes to Dr. Alfa – all funds handled by the St. Boniface Research Centre).

Overview:

- Surgical Instruments:
  - data on soiling levels after patient-use
- Cleaning efficiency:
  - automated washers
- What can users do?

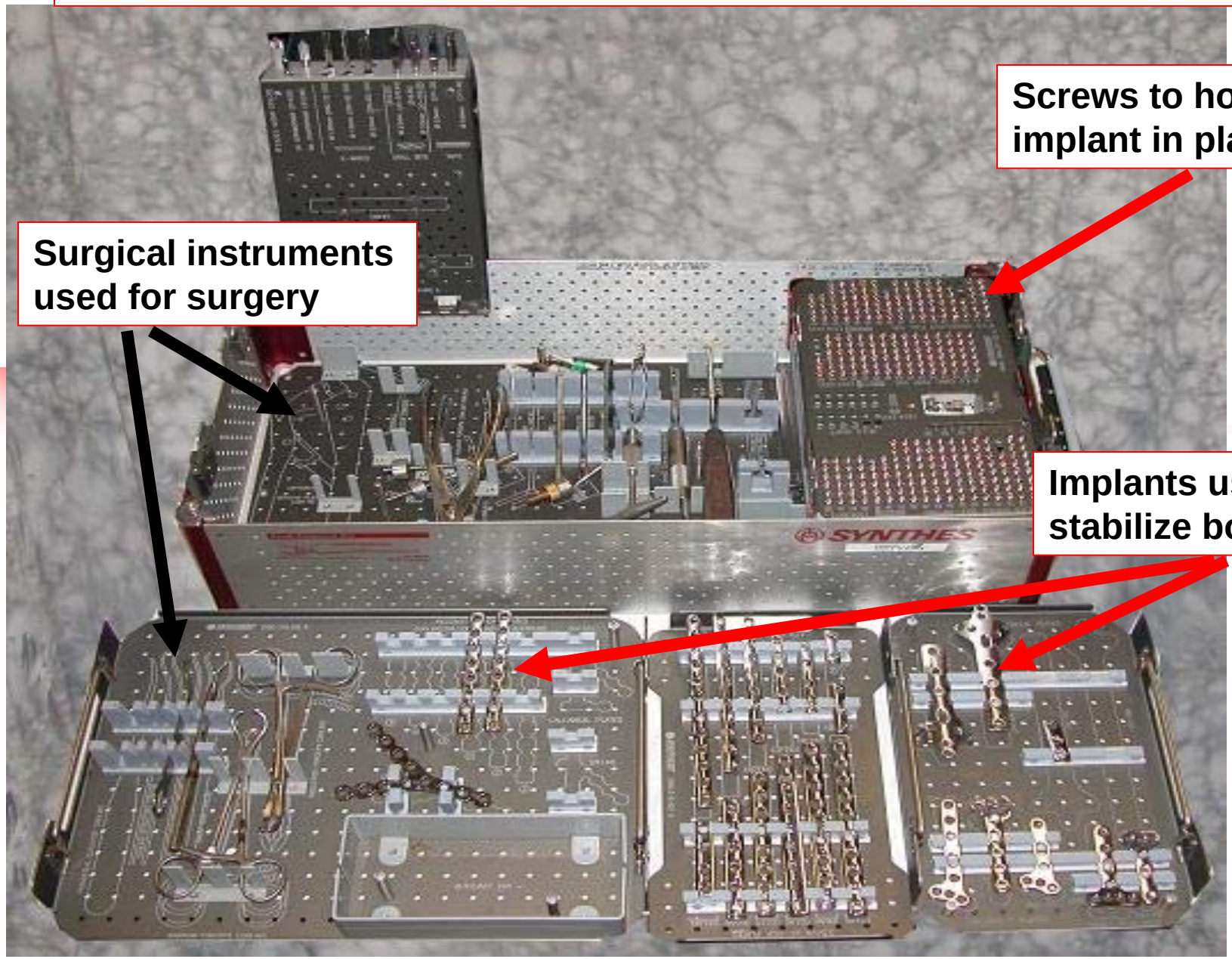
Surgical Instrument Sets:
When You Open Pandora's Box.....

Hear no evil....

See no evil....

Speak no evil....

Example: Fragment Tray Surgical set (ORSY-690SMSET)



Picture from Synthes website; March 2, 2010

Reprocessing of Instrument Trays: Washer Disinfectors

Every time instrument set is exposed to:

CLEANING:

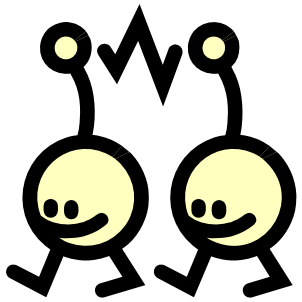
- **Pre-treatment: enzymatic detergent**
- **Cleaning: chemical detergent**
- **Final Rinse: Tap water (or Deionized, RO)**

STERILIZATION:

- **Steam**

What Post-cleaning Residuals are Relevant?

- **Viable Microorganisms:**
  - previous patient
  - water



- **Organic:**
  - previous patient
  - water
  - detergent
  - biofilm (washer or instruments)

Published Data?

- Surgical instrument residuals?
  - pre-cleaning vs post-cleaning
- What level of residuals is acceptable after completion of cleaning?

Study to evaluate patient-used instrument residuals pre and post cleaning

Curved Iris

Skin Hook

Needle driver

Curved Mosquito

Adson toothed fine

Pictures from company website

Plastics Instrument Set used in the Emergency Dept

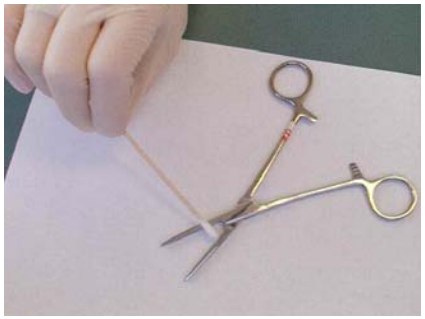
Reprocessed using automated instrument washer in the Central Processing Department

Tested the Five most commonly soiled instruments in the tray set

Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Study Method:

- Five instruments/set sampled
- Total of 10 patient procedures evaluated
  - 5 patient-used before cleaning
  - 5 patient-used post-cleaning
- Surface area swabbed: 1cm^2
- Each sample assayed quantitatively for: Protein, Hemoglobin, Carbohydrate, LPS (i.e. endotoxin)



Residuals on Patient-used instruments post-cleaning: Automated washer

Plastics Tray **Instrument type:** **(visible soil after use)**	**Protein: (µg/cm²)** **Average for 5 devices**		**Hemoglobin: (µg/cm²)** **Average for 5 devices**	
	Before cleaning	***After cleaning***	***Before cleaning***	***After cleaning***
1. **Curved Mosquito forcep** **1/5 visibly soiled:** **(1 device; 1+)**	**7.04**	**0.18**	**0.00**	**0.00**
2. **Fine Needle Driver** **5/5 visibly soiled:** **(2 devices; 1+, 3 devices; 3+)**	**49.96**	**0.00**	**13.26**	**0.00**
3. **Curved Iris Scissors** **2/5 visibly soiled:** **(2 devices; 3+)**	**373.78**	**0.14**	**110.96**	**0.00**
4. **Toothed Adson forcep (fine)** **4/5 visibly soiled:** **(2 devices; 1+, 2 devices; 2+)**	**55.38**	**1.04**	**9.90**	**0.44**
5. **Skin Hook** **1/5 visibly soiled:** **(1 device; 1+)**	**3.36**	**3.16**	**0.36**	**0.12**
Average:	**97.90**	**0.90**	**26.90**	**0.11**

Residuals on Patient-used instruments post-cleaning: Automated washer

Plastics Tray **Instrument type:** **(visible soil after use)**	**Carbohydrate: (µg/cm²)** **Average for 5 devices (SD)***		**Endotoxin: (EU/cm²)** **Average for 5 devices (SD)**	
	Before cleaning	***After cleaning***	***Before cleaning***	***After cleaning***
1. Curved Mosquito forcep **1/5 visibly soiled:** **(1 device; 1+)**	**120.52**	**301.16**	**13.68**	**18245.32**
2. Fine Needle Driver **5/5 visibly soiled:** **(2 devices; 1+, 3 devices; 3+)**	**116.86**	**336.86**	**10.62**	**23667.74**
3. Curved Iris Scissors **2/5 visibly soiled:** **(2 devices; 3+)**	**146.68**	**352.10**	**32.40**	**20.42**
4. Toothed Adson forcep (fine) **4/5 visibly soiled:** **(2 devices; 1+, 2 devices; 2+)**	**169.40**	**138.76**	**23.44**	**13.14**
5. Skin Hook **1/5 visibly soiled:** **(1 device; 1+)**	**141.14**	**193.46**	**10.58**	**25373.88**
Average:	**138.92**	**264.47**	**18.14**	**13464.10**

Conclusions from Study:

- Not all WD cycles had this problem
  (84% of instruments had higher Carb and 60% had higher Carb & LPS residuals post cleaning vs pre-cleaning Avg level)
- Likely reflected inadequate water quality → ? Final rinse water
- ? Biofilm in lines/water holding tank?

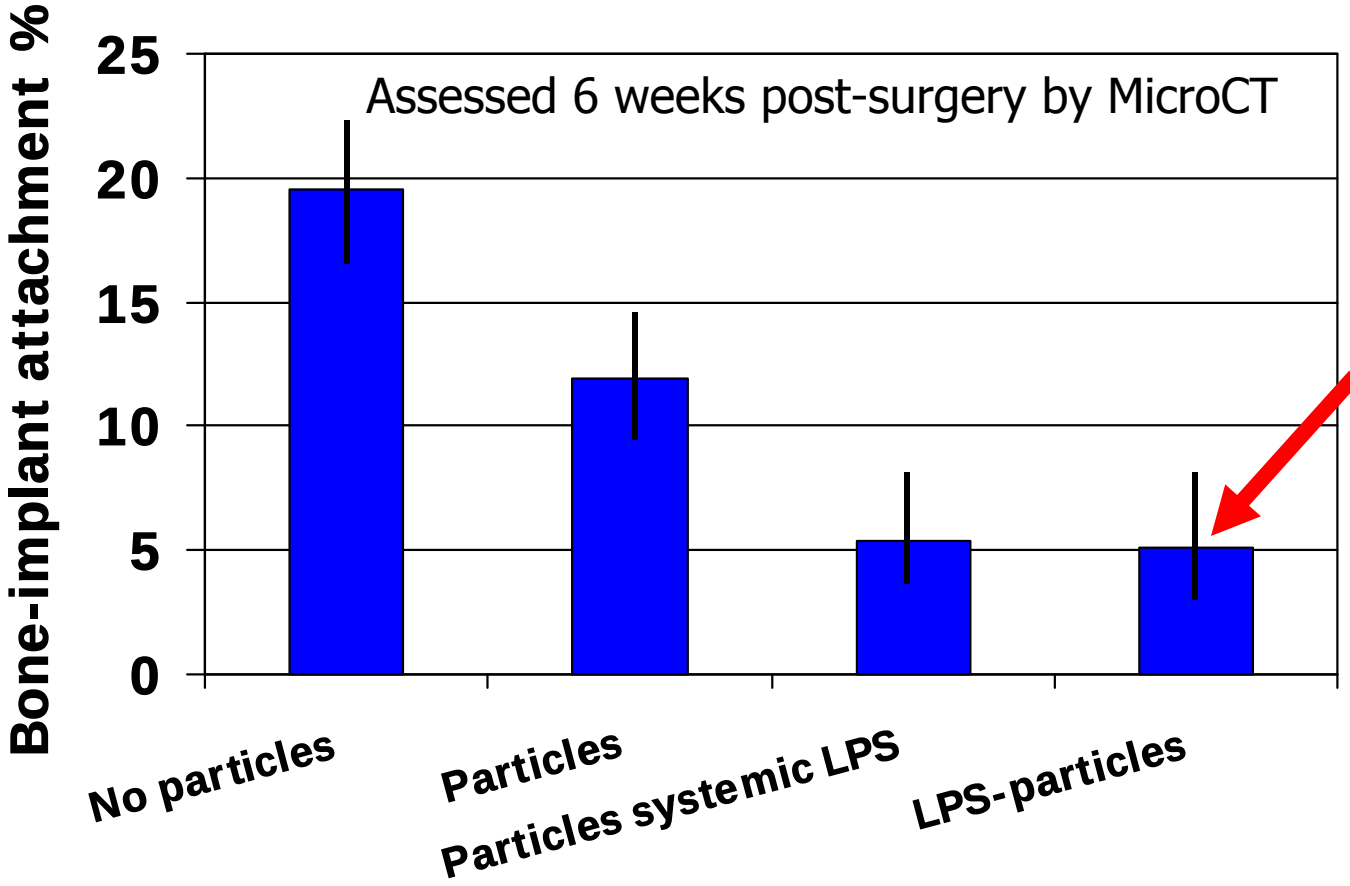
Alfa et al, Cleaning efficacy of medical device washers in N American healthcare facilities. J Hosp Infect 2009

Take Home Message: Residuals Post-cleaning

- Post-cleaning residuals may remain on instrument if automated washer cleaning is ineffective
- Steam sterilization → "sterile crud"
- Endotoxin (LPS); not destroyed by steam sterilization→ still causes inflammatory response
- Proteins etc are denatured but still remain antigenic

Impact of LPS-particles on implant attachment in bone

RAT MODEL;
LPS-coated particles + titanium pins implanted in femoral canal



Endotoxin on implant causes inflammatory response that interferes with attachment.

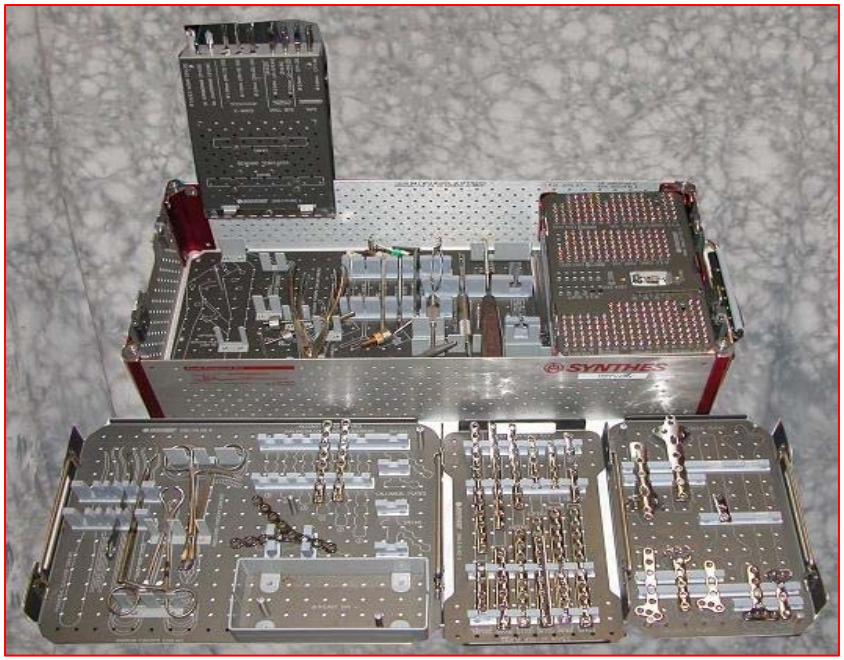
Xing Z et al J Orthop Res 2006;24:959-966

Summary of Published Literature:

- Rat Model: LPS and particulate wear debris → inflammatory response/loosening
- LPS does stimulate inflammatory response→ TNFα, IL-1, IL-6, PGE_2
- High LPS residuals on surgical instruments after final rinse in automated washer-disinfector can occur

Pandora's Box!!

- Do residuals from reprocessing contribute to adverse patient reactions?



More Scientific Data needed:
Assess surgical instruments and implanted items that are repeatedly reprocessed → any LPS or organic residuals?

What can Users do??

- Monitoring to assure the WD is cleaning properly
- Ensure final rinse water of adequate quality

References

General Reprocessing

- AAMI TIR12:2004 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed*
- Red brochure*: Proper Maintenance of Instruments, 8ed.* http://www.a-k-i.org/englisch/lit.htm
- Spaulding EH. *Chemical disinfection of medical and surgical materials [Chapter 32].* In: Lawrence CA, Block SS, eds. Disinfection, sterilization and preservation. Philadelphia, PA: Lea & Febiger, 1968: 517–31
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings (April 30, 2006)
- CDC (HICPAC) *Guideline for Disinfection and Sterilization in Healthcare Facilities 2008*
- ISO 15883-1:2006. *Washer–disinfectors, Part 1: General requirements, definitions and tests.*

References

Reprocessing Instructions & Methods

- AAMI TIR12:2004 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed*
- ANSI/AAMI ST81:2004 *Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices*
- ANSI/AAMI ST79:2006 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
- *Canadian Standards Association Inc. Publishers Mississauga, ON. CSA Z314.8-08 Decontamination of Reusable Medical Devices. 2008.*

Cleaning

- AAMI TIR34:2008 *Water for reprocessing medical devices*
- AAMI TIR30:2003 *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*
- ISO/TS 15883-5:2005 *Washer-disinfectors — Part 5:Test soils and methods for demonstrating cleaning efficacy of washer–disinfectors*